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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,125	11/18/2003	**Jun Kashimura**	SOE10009	2759

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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,125	KASHIMURA ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *19-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 29-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed Jul. 30, 2009 are acknowledged and have been fully considered. Claims 1-40 are now pending. Claims 1-8, 12-14, and 18 are amended; claims 19-28 are withdrawn; claims 29-40 have been added. Claims 1-18 and 29-40 are now under consideration.

Information Disclosure Statement

The references lined-through on the information disclosure statement was not considered because it was not clear that the NPL reference provided corresponded to that listed on the IDS (i.e. the page numbers do not match, and no other identifiers such as journal, volume #, etc. appear on the NPL document). This listing does not appear to conform to 37 C.F.R. 1.98(b).

OBJECTIONS/REJECTIONS WITHDRAWN

The objection to the specification (i.e. the use of the trademark PALATINOSE) is withdrawn, in light of the amendments to the specification filed Jul. 30, 2009.

The rejection of claims 1-18 under 35 U.S.C. 101 is withdrawn, in light of the claim amendments.

The rejection of claims 1-18 under 35 U.S.C. 112, 2nd paragraph is withdrawn, in light of the claim amendments.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claims 1-18 under 35 U.S.C. 102(b) over LINA is maintained as discussed below.

The rejection of claims 1-18 under 35 U.S.C. 102(b) over BUCKE is maintained as discussed below.

The rejection of claims 1-18 under 35 U.S.C. 102(b) over BRENDEL is maintained as discussed below.

Claim Rejections - 35 USC § 102 (Maintained)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by LINA (Lina, B. A. R., *et al.* (2002). Food and Chem. Tox. 40(10); 1375-1381; published online May 2, 2002).

1. Lina teaches that isomaltulose (i.e. PALATINOSE®) is a natural occurring disaccharide that has been used as a sugar in Japan since 1985 (abstract). Lina teaches that isomaltulose is particularly suitable as a non-cariogenic sucrose replacement in products for diabetics, in part because blood glucose levels in humans after oral administration of isomaltulose are attenuated compared to sucrose administration (abstract; p. 1377, left col., 1st full paragraph; p. 1379, left col., 2nd paragraph). Lina teaches the use of isomaltulose as an alternative sugar in most sweet foods (abstract; p. 1375, right col., middle paragraph). Lina also teaches compositions comprising both isomaltulose and sucrose (i.e. wherein the two compounds are administered simultaneously) (p. 1377, right col., last paragraph). Lina teaches administration of isomaltulose at levels of up to 8.1 g/kg body weight in rats and up to 1 g/kg in humans (p. 1378, right col.). It is noted that the term "carrier" has not been defined in the instant specification. Merriam-Webster defines a carrier as, *inter alia*, a usually inactive accessory substance: vehicle. Thus, the "carrier" of the instant claims can be virtually any substance that acts as a vehicle for isomaltulose. Lina teaches administering isomaltulose in the diet in the form of foods (p. 1377, left col., bottom par., right col., top and bottom pars.; p. 1378, left col., section 3.2, right col., top par.). The diet/foods of Lina meet the language of the instant claims.

2. It is noted that the "wherein" clauses in claims 1-11 and 13-17 are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative

to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

3. Additionally, claims 7, 12, and 13 require the presence of a foodstuff composed of a carbohydrate "having an α-1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides." This recitation embraces carbohydrates having 0% of the recited ratio (i.e. carbohydrates which do not have any α-1,6-glucosyl bonds). Thus *any* carbohydrate (e.g. sucrose) meets the claim. In addition to sucrose, Lina also teaches replacing part of the starch in foods with isomaltulose (p. 1378, section 3.2) and teaches feeding 10%, 20%, 30%, or up to 56% isomaltulose as part of feed/foodstuffs (p. 1376, right col. 1st full par.; p. 1377, bottom of left and right cols.; p. 1378, top of left col.; p. 1379, left col. bottom par.).

4. It is further noted that the ability of isomaltulose to reduce an increase in blood glucose level, or reduce body fat accumulation is an inherent property of the compound. Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Thus, any composition comprising isomaltulose would have this

property and reads on the claims. Claims 1-9 and 13-15 are anticipated by Lina. Claims 10-12 and 16-18 are also anticipated since they merely present additional "wherein" clauses that recite intended use and are not afforded patentable weight.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Lina does not teach the amount of isomaltulose instantly recited in the claims (response, p. 20).

Applicants are incorrect. Applicants admit that,

> "...the Lina Article discloses feeding rats up to 8.1 g/kg body weight/day of isomaltulose (Lina Article, at 1378, left col., lines 11-15) and giving humans as little as 0.25 g/kg/dose of oral isomaltulose (Lina Article, at 1378, right col., lines 26-32)." (response, p. 20, bottom par.)

Even the lowest amount taught by Lina (i.e. 0.25 g/kg body weight, pointed to by applicants) is more than applicants' highest claimed amount of 0.167 g/kg (i.e. 10 g per 60 kg body weight). Thus, applicants' statement that Lina does not teach or suggest, "5 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 1-3, 7 and 8, and "10 g or more of isolmaltulose per 60 kg of body weight of an individual as an active ingredient" as recited by claims 4-6, 13 and 14 is completely without merit because Lina teaches these amounts, contrary to applicants' incorrect assertion.

Applicants argue that the "wherein" clauses should be given patentable weight because they reflect properties of the composition (response, p. 21-22). Applicants further argue that the ability of isomaltulose to reduce an increase in blood glucose level

and body fat accumulation is not inherent (response, p. 22-23).

The examiner disagrees. Applicants are reminded that they have elected product claims, not method claims, for prosecution on the merits (see applicants' response to the restriction requirement filed Jun. 23, 2008). MPEP 2106(II)(C) states, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." The MPEP further provides examples of language that may raise a question as to the limiting effect of the language in a claim. Included among these examples are (A) statements of intended use or field of use and (C) "wherein" clauses. As discussed in the prior Office Action, the instant "wherein" clauses do nothing more than recite the intended use and desired outcome of the use of the claimed *product*. Being product claims, the intended use of the product is not at issue. As such, these limitations do not state a condition material to patentability and are rightly afforded no patentable weight in the claims. In response to applicants' argument that the "wherein" clauses must be afforded patentable weight, applicants are reminded that, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In response to applicants' arguments regarding the inherency of the glucose level reducing and anti-fat properties of isomaltulose, applicants are reminded that "Products of identical chemical composition can not have mutually exclusive properties. A

chemical composition and its properties are inseparable." See MPEP § 2113.01(II). It is noted that applicants are being inconsistent in their reasoning. On one hand, applicants state that the effects of the invention on blood glucose and fat accumulation are properties of the composition (see pgs. 22, 26-27, and 29 of the response filed Jul. 30, 2009). On the other hand, applicants argue that these properties are present only when a certain threshold (i.e. an amount of isomaltulose) is exceeded. Applicants point to pars. [0055] and [0065] of their specification in support of this assertion. Due to the inseparable nature of isomaltulose and its chemical properties, the effects of isomaltulose must be present, no matter what quantity of isomaltulose is consumed. This is supported by applicants' specification (e.g. pars. [0055] and [0065]), which states that in order to be *significant*, the intake of isomaltulose must be above a certain level. Below this level of isomaltulose, the effect is still present, it is just not (statistically) significant. Thus, applicants' own specification suggests that the claimed properties of isomaltulose are inherent in support of the examiner's position. It is noted that there is nothing in the instant claims regarding how much of a decrease in either the blood glucose level or fat accumulation must occur.

Nonetheless, the only structural limitation implied by applicants' amendment is relates to the amount of isomaltulose present in the composition. Applicants suggest that so long as the amount of isomaltulose exceeds the minimum dose recited, the properties are present (see paragraph bridging pgs. 22-23 of the response). Lina teaches the claimed amount(s) of isomaltulose. Thus, the properties of blood glucose reduction and fat accumulation reduction are inherent in Lina's compositions. Thus,

even if the properties of isomaltulose recited by applicants can be shown not to be inherent (which applicants have not done), these properties must be present in the prior art compositions by applicants own reasoning.

Applicants argue that Lina reports that, for rats, ingestion of up to 8.1 g/kg body weight/day of isomaltulose did not affect body fat accumulation (response, p. 23).

Again, applicants' statement is incorrect. Lina teaches that body *weight* was not affected by isomaltulose. Lina says nothing about body *fat*. Applicants' statements to the contrary are inaccurate. Moreover, if applicants' arguments with respect to Lina's teachings were accurate, they would represent evidence that applicants are not enabled for their intended use.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by BUCKE (U.S. 4,587,119; Issued May 6, 1986).

1. Bucke discloses the use of isomaltulose as a whole or partial replacement for sucrose in food products for human or animal consumption (abstract). Bucke teaches the use of isomaltulose in premixes, such as cake mixes and in beverages (col. 2, lines 4-14; col. 4, lines 32-39). Furthermore, Bucke discloses several embodiments in which the food material comprises an isomaltulose weight ratio of 10% or more relative to the total weight of the carbohydrate in the food material (e.g. Examples 1, 3, 4, 5, and 7). Any of these examples provide the instantly claimed amounts of isomaltulose. The various ingredients of Bucke meet the language of the instant claims regarding a carrier. Bucke anticipates claims 1-18.

2. It is noted that the "wherein" clauses in the claims are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

3. Additionally, claims 7, 12, and 13 require the presence of a carbohydrate "having an α-1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides." This recitation embraces carbohydrates having 0% of the recited ratio (i.e. carbohydrates which do not have any α-1,6-glucosyl bonds). Thus any carbohydrate (e.g. sucrose) meets the claim.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Bucke does not disclose isomaltulose compositions comprising either a pharmaceutical ingredient or a carrier (response, p. 25). Applicants argue that the "wherein" clauses should be given patentable weight (response, p. 26)

Applicants' arguments were addressed *supra* in conjunction with Lina, and are incorporated herein. Applicants are invited to explain how any one of the ingredients

taught by Bucke could not be construed as a carrier, particularly given the lack of a definition for this term in the specification.

Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by BRENDEL (U.S. 2002/0192344; Filed Mar. 29, 2002).

4. Brendel discloses processes for preparing food products with reduced calorific value by replacing the high-calorie substances in the food produces with related substances of reduced calorific value (abstract). Brendel teaches the use of isomaltulose as a replacement for sugars in food products such as biscuits (paragraphs [0026] and [0030]-[0032]; claim 9). Brendel teaches the use of isomaltulose along with maltodextrins and/or starches such as wheat flour (i.e. carbohydrates having an α-1,6-glucosyl bond ratio from 0% to less than 50% relative to the total bonds among the constituent saccharides as defined in paragraph [0062] of the instant specification). Brendel teaches that isomaltulose may comprise 0.5-98% by weight (relative to the total weight of the foodstuff, which represents a weight ratio of at least 10% or more relative to the carbohydrate contained in the food (paragraphs [0026] and [0030]-[0032]; claim 9; Examples 1, 4 and 6). Any of these examples provide the instantly claimed amounts of isomaltulose. The various ingredients of Brendel meet the language of the instant claims regarding a carrier. Brendel anticipates claims 1-18.

5. It is noted that the "wherein" clauses in claims 1-11 and 13-17 are not afforded patentable weight. For example the limitation in claim 1 "...wherein when said reducer is ingested by an individual before or after or simultaneous with consuming a carbohydrate having an α-1,6-glucosyl bond ratio of from 0% to less than 50% relative

to the total bonds among constituent saccharides, said reducer reduces an increase in blood glucose level of the individual caused by consuming said carbohydrate" is not afforded patentable weight. Analogous situations exist in claims 2-11, and 13-17. The MPEP states that such "wherein" clauses raise a question as to the limiting effect of the claim language. See MPEP § 2111.04. In the instant case, these phrases merely reflect the intended use and desired outcome of ingesting the isomaltulose composition.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Brendel does not disclose isomaltulose compositions comprising either a pharmaceutical ingredient or a carrier (response, p. 28). Applicants argue that the "wherein" clauses should be given patentable weight (response, p. 28-29)

Applicants' arguments were addressed *supra* in conjunction with Lina, and are incorporated herein. Applicants are invited to explain how any one of the ingredients taught by Brendel could not be construed as a carrier, particularly given the lack of a definition for this term in the specification.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lina in view of SHIMIZU (U.S. 2003/0180432; Filed Feb. 6, 2003).

6. The teachings of Lina are presented *supra*. Lina does not explicitly teach the inclusion of gums or vitamins in the compositions. However, Lina clearly describes the use of isomaltulose as a substitute for various sugars in foodstuffs, for example for diabetics and prediabetics (abstract; p. 1375, right col., last sentence of middle par.; p. 1376, left col., top par.). Since Lina teaches the use of isomaltulose in foodstuffs, it

would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include components typically found in edible compositions, such as gums and/or vitamins.

7. For example, Shimizu discloses prepared soymilks and soymilk beverages containing palatinose (abstract; pars. [0010] and [0017]). Shimizu teaches that the compositions can comprise food additives such as gums and vitamins (par. [0022]). The artisan would be motivated to add gums and/or vitamins based on the form of the foodstuff being produced. Thus if an artisan wanted to prepare a soymilk product, it would be no more than routine to add typical food additives such as gums and vitamins to the composition to adjust the desired oganoleptic properties of the final food product. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add gums and/or vitamins, to isomaltulose-containing foodstuffs per the teachings of Lina and Shimizu to provide a suitable dietary product.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a

reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue unexpected results, which are only germane to the 103 rejections (response, p. 30).

Applicants' assertion of unexpected results is not persuasive for at least the following reasons. The showing of alleged unexpected results 1) does not compare the invention to the closest prior art and 2) the alleged unexpected results are not commensurate in scope with the claims. On p. 30, applicants state that, "The present invention is based on the discovery of unknown properties pertaining to a palatinose-containing composition." Applicants are reminded that something which is old does not become patentable upon the discovery of a new property. See MPEP § 2112, which states, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >*In In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364,

1368 (Fed. Cir. 2004).

First, instead of comparing the instantly claimed invention to a known prior art composition, of which there are many, applicants submit a theoretical model and assert that it represents the expected state of the art. Applicants provide no evidence to support the assertion that their hypothetical model is what would be expected by a skilled artisan. Thus, applicants have not properly compared their invention to the available art. Second, the only data presented by applicants relate to the situation where isomaltulose is ingested "substantially simultaneously" with glucose. Not only do the claims encompass ingestion of isomaltulose at other times (i.e. before and after a carbohydrate), but the claims are not limited to only glucose, but broadly recite *any* carbohydrate. Furthermore, it is not apparent that the data relate to a composition comprising either a gum or a vitamin as recited in claims 29-40. It cannot be said that applicants' data is commensurate in scope with the claims, even if it were convincing.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

Claims 1-18 and 29-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-3, 7, and 8, the recitation, "5 g or more of isomaltulose per 60 kg of body weight of an individual" renders the claims indefinite. Likewise, the recitation "10 g or more of isomaltulose per 60 kg of body weight of an individual" in claims 4-6, 13, and 14 is indefinite. These recitations are analogous to method steps in a product claim

since they imply the active step of administering the composition to an individual. However, it is noted that administration is not required by the claims. Administration to an individual is an intended use of the claimed product, which carries no patentable weight. Furthermore, the amounts of isomaltulose (i.e. 5 or 10 g) are linked to a particular body weight of an individual, but administration to a particular individual is not actually required. Thus, the plain meaning of the claim requires different amounts of isomaltulose per individual. Since administration to a person is not actually required by the claims, it is not clear how much isomaltulose must be present to meet the claim.

In light of applicants' arguments, the claims will be construed as limiting the amount of isomaltulose in the composition. Due to the issues raised in this indefiniteness rejection, the amount will be construed as 0.083 g/kg (i.e. 5g/60kg) isomaltulose or 0.167 g/kg (10g/60kg) as applicable per the claims, or any amount that could reasonably supply these doses to a subject.

Summary/Conclusion

Claims 1-18, and 29-40 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin S Orwig/

/David J Blanchard/
Primary Examiner, Art Unit 1643